REMARKS

I. Status of Claims

This is in Response to the non-final Office Action dated March 23, 2011. A petition for two month extension of time and the corresponding fees accompany this Amendment.

By virtue of the present Amendment, claim 1 has been amended to recite that the composition exhibits a fine particle fraction (MD) of at least 40. Support for this amendment can be found of page 14, lines 23 to 24 and page 34, lines 11-13 of the international application as filed. Claim 1 has also been amended to recite a tapped density of at least 0.5 g/cc. Support can be found in Figures 7a-7c of page 68-70 of the international application as filed. Claim 1 has further amended to recite that the composition must contain between 90 and 98% w/w heparin and between 2 and 10% w/w leucine. Support for this amendment can be found on page 34, lines 11-13 of the international application as filed.

Claims 2, 25 and 26 have been canceled in the present Amendment

It is submitted that no new matter has been added by virtue of the present amendments.

II. Rejection under § 112, first paragraph

In the Office Action, the Examiner has rejected claim 1-2, 6-7, 11-15 and 25-29 under 35 U.S.C.112, first paragraph, as failing to comply with the written description requirement.

While Applicants do not agree that with the Examiner's position concerning lack of written description, for the purpose of expediting prosecution, Applicants have deleted the limitation "wherein the composition has a fine particle fraction (metered dose) of between 40 and 70%" and replaced it with a "at least 40 %", as suggested by the Examiner on page 3 of the Office Action.

III. Rejection under § 112, fourth paragraph

Claims 6-7, 25 and 27-29 were rejected under 35 U.S.C. 112, fourth paragraph, as failing to further limit claim 1.

Claim 1, in pertinent part, recites a fine particle fraction (<5 μm) of at least 40% and wherein the powder has a tapped density of at least 0.5 g/cc". Applicants believe that the rejected claims all properly limit claim 1 as amended.

Specifically, claim 6 calls for "90% of the resulting dried particles have a size of less than 5μm, as measured by laser diffraction" and claim 7 calls for "90% of the resulting dried particles have a size of less than 2.5 μm, as measured by laser diffraction." These are both narrower than the recitations of claim 1 set forth above.

Claim 25 has been canceled and therefore the rejection of this claim is moot.

With regard to claims 27-29, these claims also further limit claim 1 as they recite, in pertinent part:

Claim 27: "a fine particle fraction of at least 50%".

Claim 28: "a fine particle fraction of at least 60%".

Claim 29: "a fine particle fraction of at least 70%".

In view of the above, Applicants respectfully request withdrawal of this rejection.

IV. Rejection under 35 U.S.C. § 103 over Staniforth in view of Tarara

Claims 1, 11-14, 25, and 27-29 were rejected under 35 U .S.C. 103(a) as being unpatentable over Staniforth (EP 1 213 012) (pub. June 12, 2002) in view of Tarara et al. (US 6,565,885).

In response, Applicants explain that the Staniforth reference does not teach or suggest a formulation comprising 90-98% w/w heparin and 2-10% leucine as set forth in present claim 1. Further, the Staniforth reference does not teach or suggest a tapped density, let alone a tapped density of at least 0.5 g/cc.

With regard to the Tarara reference, Applicants point out that this reference does not disclose or suggest the use of heparin and therefore cannot cure the deficiency of the Staniforth reference. Further, one of skill in the art would have no reason to believe that the teachings of the Tarara reference would be applicable to the teachings of Staniforth, as heparin is a very sticky molecule with different properties than the compounds disclosed in the Tarara reference.

Applicants additionally point out that the Tarara reference purportedly teaches the production of small aerodynamically light particles which aerosolize with ease and which have excellent inhalation properties through the incorporataion of a blowing agent. The Tarara reference purportedly achieves this by the use of a blowing agent to create perforated microstructures having a bulk density of **less than 0.5 g/cm^3** (see, column 4, lines 20 to 24 of the Tarara reference) In other words, the Tarara reference teaches one of skill in the art to use low-density powders for inhalation because these provide superior aerodynamic performance when used in inhalation therapy (see column 4, lines 11-14 of the Tarara reference) and which have enhanced stability (see column 4, lines 14-19 of the Tarara reference). As a result, even if one of skill in the art were to combine the teaching of the Staniforth and Tarara references, the result would be a pharmaceutical composition containing porous particles with a density below 0.5 g/cc. Other particles would be seen as unsuitable in view of the combined teachings of these references.

In view of the above, claim1 is not rendered obvious obvious in view of the teachings of the Staniforth reference in view of the Tarara reference. As the remainder of the claims depend, directly or indirectly, from claim 1, Applicants respectfully request that the rejection of these claims also be withdrawn.

V. Rejection under 35 U.S.C. § 103 over Staniforth in view of Tarara in further view of Wiedmann

Claim 2 was rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth (EP 1 213012) (pub. June 12, 2002) in view of Tarara et al. (US 6,565,885) as applied to claims 1, 6-7, 11-14, 25 and 27-29 above, and further in view of Wiedmann et al. (Pharm. Dev. & Tech.).

For the purpose of expediting prosecution of the present application, claim 2 has been canceled in the present Amendment. Therefore, this rejection is moot.

VI. Rejection under 35 U.S.C. § 103 over Staniforth in view of Tarara in further view of Kuo

Claim 15 was rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth (EP 1 213012) (pub. June 12, 2002) in view of Tarara et al. (US 6,565,885) as applied to claims 1, 6-7, 11-14, 25 and 27-29 above, and further in view of Kuo et al. (US 6,518,239).

Claim 15 recites "[a] method as claimed in claim 1, wherein the method further comprises adjusting the moisture content of the spray dried particles." As Claim 15 depends from claim 1, it is not rendered obvious by the combined teachings of the Staniforth reference in view of the Tarara reference for the reasons cited above.

In the Office Action, the Examiner additionally cites to the Kuo reference for its teaching of a method for increasing dispersibility of an active-agent containing formulation for administration to the lung and for its teaching that the spray dried particles may be spray freeze dried. However, the Kuo reference does not cure the deficiencies recited above for the

combination of the Staniforth reference in view of the Tarara reference in terms of claim 1. As claim 15 depends from claim 1, the addition of the Kuro reference to the Staniforth and Tarara references cannot render claim 15 obvious.

VII. Rejection under 35 U.S.C. § 103 over Staniforth in view of Tarara in further view of Kodas

Claim 26 was rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth (EP 1 213012) (pub. June 12, 2002) in view of Tarara et al. (US 6,565,885) as applied to claims 1, 6-7, 11-14, 25 and 27-29 above, and further in view of Kodas et al. (US 6,051,257).

Applicants point out that this rejection is moot as claim 26 has been cancelled and the subject matter of claim 26 has been incorporated into current claim 1 in the present Amendment. As such the rejection is moot and Applicants respectfully request that it be withdrawn.

Applicants additionally point out, however that the Kodas reference teaches one of skill in the art to use particles having a density greater than 1 g/cc while the Tarara reference teaches one of skill in the art to use porous particles with low density (less than 0.5 g/cc). One of skill in the art would have no reason to combine the very different teachings of these references.

Further, the Kodas reference requires the particles used should contain less than 20 % w/w of the active ingredient as the bulk of the material should be "other materials such as a matrix material (e.g. sugars), stabilizers and the like" (see, column 17, lines 55-59 of the Kodas reference). In contrast, the claims of the present application require the particles to contain at least 90% w/w heparin, which is the active ingredient.

Thus, one of skill in the art combining the teachings of the Staniforth and Kodas references would inevitably arrive at a very different formulation than that of claim 1, and the claims dependent thereon such that these claims.

VIII. Novelty over Staniforth

Although there is no anticipation rejection presented in the present Office Action, Applicants wish to clarify the following point in the hopes of expediting prosecution.

In the response to the previous Office Action, Applicants added the distinguishing feature of 40-70% fine particle fraction to claim 1 and noted this difference in distinguishing over the Staniforth reference. In the present Amendment, claim 1 has been amended, as suggested by the Examiner, to read "at least 40% fine particle fraction". Applicants wish to point out that the current claim 1 requires a tap density of at least 0.5 g/cc, which is not disclosed in Staniforth. Therefore, the present claims cannot be anticipated by the Staniforth reference.

Conclusion

This Response is being submitted in response to the Office Action dated March 23, 2011 in the above-identified application. Concurrently with this Response, Applicants submit a petition for two-month extension of time for filing a response and the corresponding fees. If it is determined that any additional fee is due in connection with this filing, the Commissioner is authorized to charge said fees to Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly requested.

Respectfully submitted,
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